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ATTORNEY DOCKET NO. FIRST NAMED INVENTOR CONFIRMATION NO. APPLICATION NO. FILING DATE Oren Globerman 9263 09/890,318 07/25/2001 **EXAMINER** 02/10/2005 7590 44909 FENSTER & COMPANY INTELLECTUAL PROPERTY 2002 LTD. PHILOGENE, PEDRO C/O REED SMITH LLP **ART UNIT** PAPER NUMBER 599 LEXINGTON AVENUE, 29TH FLOOR

DATE MAILED: 02/10/2005

3732

Please find below and/or attached an Office communication concerning this application or proceeding.

		Application No.	Applicant(s)	
Office Action Summary		09/890,318	GLOBERMAN ET AL.	
		Examiner	Art Unit	
		Pedro Philogene	3732	
Period fo	The MAILING DATE of this communication app or Reply	ears on the cover sheet with the c	orrespondence address	
THE - External after - If the - If NC - Failury	ORTENED STATUTORY PERIOD FOR REPLY MAILING DATE OF THIS COMMUNICATION. Insigns of time may be available under the provisions of 37 CFR 1.13 SIX (6) MONTHS from the mailing date of this communication. Is period for reply specified above is less than thirty (30) days, a reply of period for reply is specified above, the maximum statutory period we are to reply within the set or extended period for reply will, by statute, reply received by the Office later than three months after the mailing ed patent term adjustment. See 37 CFR 1.704(b).	6(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days all apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).	
Status				
1)[\bigsilon]				
<u> </u>	a) This action is <b>FINAL</b> . 2b) ⊠ This action is non-final.			
3)	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.			
	ciosed in accordance with the practice under E	x parte Quayle, 1955 C.D. 11, 40	00 O.G. 210.	
Disposit	ion of Claims			
5)⊠ 6)⊠ 7)⊠	Claim(s) 1-89 and 100-173 is/are pending in the application.  4a) Of the above claim(s) is/are withdrawn from consideration.  Claim(s) 73-89 and 100-173 is/are allowed.  Claim(s) 1-8,11,12,15,17,18,22,23,34-55,58-60 and 63-72 is/are rejected.  Claim(s) 9,10,13,14,16,19-21,24-33,56,57,61,62 is/are objected to.  Claim(s) are subject to restriction and/or election requirement.			
Applicat	ion Papers			
9)[	The specification is objected to by the Examine	r.		
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.				
	Applicant máy not request that any objection to the			
11)	Replacement drawing sheet(s) including the correct.  The oath or declaration is objected to by the Ex			
Priority (	under 35 U.S.C. § 119		•	4
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>				
Attachmen				
· -	ce of References Cited (PTO-892) ce of Draftsperson's Patent Drawing Review (PTO-948)	4) L Interview Summary Paper No(s)/Mail D	·	
3) Infor	mation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) or No(s)/Mail Date		Patent Application (PTO-152)	

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## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8,11,12,15,17,18,22,34,35,37,39,40,42,47-49,58,68 are rejected under 35 U.S.C. 102(b) as being anticipated by Bachmann et al. (5,759,186).

With respect to claim 1, Bachmann et al disclose an apparatus (1) for controlling the deformation of an implant during deployment thereof, comprising a force application mechanism (3) for applying deformation force to the implant, by axial motion of a force applicator against the implant; and a restraint element positioning mechanism; as best seen in FIG.5, that positions a restraining element such that the deformation of the implant is controlled by restraint of the restraining element on allowable deformation; and a synchronizer; as best seen in FIGS.7,8, that synchronizes the motion of the restraining element and the force applicator, to achieve a desired deformation of the implant.; as set forth in column 4, line 15 - column 5, line 5; column 5, line 48 – column 6, line 32, column 6, lines 51-64.

With respect to claims 2-8, 11, 12, 15, 17,18,22,34,35,37,39,40,42,47-49,58,68, Bachmann et al discloses all the limitations; as set forth in column 4, line 15 - column 5, line 5; column 5, line 48 – column 6, line 32, column 6, lines 51-64.

Claims 1, 23,38, 41, 47-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Beyar et al. (5,782,838).

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With respect to claim 1, Beyar et al disclose an apparatus (1) for controlling the deformation of an implant during deployment thereof, comprising a force application mechanism, as best seen in FIGS.1,5-9, for applying deformation force to the implant, by axial motion of a force applicator against the implant; and a restraint element positioning mechanism; as best seen in FIG.4, that positions a restraining element such that the deformation of the implant is controlled by restraint of the restraining element on allowable deformation; and a synchronizer; as best seen in FIGS5-9, that synchronizes the motion of the restraining element and the force applicator, to achieve a desired deformation of the implant.; as set forth in column 1, line 66 - column 2, line 29; column 3, lines 12-67.

With respect to claims 23,38, 41, 47-55, Beyar et al discloses all the limitations; as set forth in column 1, line 66 – column 2, line 29; column 3, lines 12-67.

Claims 1, 34-37,69-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Lenker et al. (5,683,451).

With respect to claim 1, Lenker et al disclose an apparatus (30) for controlling the deformation of an implant during deployment thereof, comprising a force application mechanism, as best seen in FIGS.1-10, for applying deformation force to the implant, by axial motion of a force applicator against the implant; and a restraint element positioning mechanism; as best seen in FIG.2, that positions a restraining element such that the deformation of the implant is controlled by restraint of the restraining element on allowable deformation; and a synchronizer; as best seen in FIG. 2, that synchronizes the motion of the restraining element and the force applicator, to achieve a desired

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deformation of the implant.; as set forth in column 6, lines29-60; column 7, line 6 – column 8, line 10; column 8, line 54 – column 9 line41; and, as best seen in FIGS.1-10.

With respect to claims 34-37, 69-72 Beyar et al discloses all the limitations; as set forth in column 6, lines29-60; column 7, line 6 – column 8, line 10; column 8, line 54 – column 9 line41; and, as best seen in FIGS.1-10.

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 43-46, 59, 60, 63-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bachmann et al. (5,759,186).

With respect to claims 43-46, 59, 60, 63-67; it is noted that Bachmann et al did not teach of a force of 20-100 Kg and a restraint having an outer diameter less than 4-7 mm; or an apparatus attached to the patient or the bed; as claimed by applicant. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to reach the optimum value, since it has been held that discovering an optimum value of an effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Also, the use of a means to attach an apparatus to a patient or a patient's bed is old and well known in the surgical art. As to the implant being a spinal implant for fusing vertebrae, it is nothing more than the intended use of the implant.

#### Response to Amendment

Applicant's arguments, see remark, filed 12/06/04, with respect to claims 73-89, 172,173 have been fully considered and are persuasive. The rejection of these claims has been withdrawn. However, after further consideration, the indication of allowability of claims 1-72 has been withdrawn. A new rejection follows (see above).

#### Allowable Subject Matter

Claims 9,10,13,14,16,19-21,24-33,56,57 61,62 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 73-89, 100-173, are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pedro Philogene whose telephone number is (571) 272-4716. The examiner can normally be reached on Monday to Friday 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin P Shaver can be reached on (571) 272-4720. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Pedro Philogene February 08, 2005

PEDRO PHILOGENE PRIMARY EXAMINER